REMARKS

This Response is submitted in reply to the final Office Action mailed on November 5, 2009. A request for continued examination ("RCE") is submitted with this Response. The Director is authorized to charge $810.00 for the RCE and $1,100.00 for the three month extension of time and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036.00667 on the account statement.

Claims 1-44 are pending in the application. Claims 5-16 and 22-44 were previously withdrawn from consideration. In the Office Action, Claims 1-4 and 17-21 are rejected under 35 U.S.C. § 101 and 35 U.S.C. 112, first paragraph. In view of the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-4 and 17-21 are rejected under 35 U.S.C. § 101 and 35 U.S.C. 112, first paragraph, because the claimed invention lacks patentable utility. In particular, the Office Action has alleged that the specification fails to teach a specific and substantial function for the protein set forth by SEQ ID NO: 2, as encoded by SEQ ID NO: 1, because the family of cysteine proteases is a large and variable family of enzymes. Applicants respectfully disagree with and traverse the rejection for at least the reasons set forth below.

MPEP 2107.I.A provides that "[a] 'specific utility' is specific to the subject matter claimed and can 'provide a well-defined and particular benefit to the public'." Additionally, MPEP 2107.01.I.B makes clear that to satisfy the "substantial utility" requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.

As the Examiner is certainly aware, it is not necessary that applicants prove the biological mechanism by which the claimed polypeptide operates in order to show utility. All that is required is that the claimed isolated peptides have a utility as has been disclosed throughout the specification and as demonstrated in the Examples. Applicants respectfully submit that the claimed polynucleotide (SEQ ID NO: 1) has a specific and substantial utility because it encodes the cysteine protease of SEQ ID NO: 2 (CcCP-1). Given that CcCP-1 is expressed at a high level in grain tissue and at a low level in the pericarp, it can be used, for example, by a skilled artisan to differentiate the two tissue types (see, specification, pages 26-27). As such, the claimed polynucleotide and polypeptide have a significant and presently available benefit to the

public. Thus, Applicants submit that a sufficient showing of utility has been made in the present specification and requests that the rejection under 35 U.S.C. § 101 and the associated rejection under § 112 be reconsidered and withdrawn.

In the Office Action, Claims 1-4 and 17-21 are rejected to under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for any polynucleotide encoding a polypeptide having at least 70% or 85% homology to SEQ ID NO: 2 or any polynucleotide comprising SEQ ID NO: 1 or comprising a sequence encoding SEQ ID NO: 2, wherein the polynucleotide encodes a cysteine protease. In particular, the Office Action asserts that the specification does not establish regions of the protein structure which may be modified without affecting the desired activity, the general tolerance of the desired activity to modification, a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function and the specification provides insufficient guidance as to which of the infinite possible choices are likely to be successful. Applicants respectfully traverse this rejection for at least the reasons set forth below.

The inquiry with respect to scope of enablement under 35 U.S.C. §112, first paragraph, is whether it would require undue experimentation to make and use the claimed invention. As discussed in detail below, a consideration of all of the factors enumerated in In re Wands demonstrates that the application, in conjunction with what was known to one of skill in the art as well as other factors, teaches how to make and use the full scope of the claimed subject matter. In the BPAI precedential decision *Ex parte Kubin, reversing* the Examiner on a finding of lack of enablement with respect to appealed claims directed to an isolated nucleic acid encoding a polypeptide at least 80% identical to the amino acids set forth in SEQ ID NO:2 (a large protein of 365 amino acids), where the polypeptide binds CD48, the Examiner stated that while:

> ...molecular biology is generally an unpredictable art (and thus was so at the time the application was filed)... the other Wands factors weigh in Appellants' favor, particularly "the state of the art" and "the relative skill of those in the art," *In re Wands*, 858 F.2d 731, 736, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), as evidenced by the prior art teachings and Appellant's Specification. The amount of experimentation to practice the full scope of the claimed invention might have been extensive, but it would have been routine. The techniques necessary to do so were well known to those skilled in the art. *Ex Parte Marek Z. Kubin and Raymond G. Goodwin* Appeal No. 2007-0819 (BPAI 2007).

As discussed in detail below, in this instance the state and knowledge of skill in the art, the relative skill in the art far exceeds any alleged unpredictability of the full scope of the claimed subject matter.

Applicants respectfully submit that polynucleotides encoding a polypeptide with at least 70% or 85% homology to SEQ ID NO: 2 are enabled by the instant specification. Procedures and methods for identifying variant polynucleotides that retain the activity of the parental nucleotide are commonly practiced by a skilled artisan (*i.e.* advanced degree in biotechnology). Such techniques are described in numerous books and other references, see, e.g., Sambrook, *et al.* Molecular Cloning: A Laboratory Manual (2nd Edition, 1989); Maniatis *et al.* Molecular Cloning: A Laboratory Manual (1982); DNA Cloning: A Practical Approach, vol. I & II (D. Glover, ed.); Oligonucleotide Synthesis (N. Gait, ed., 1984); Nucleic Acid Hybridization (B. Hames & S. Higgins, eds., 1985); Transcription and Translation (B. Hames & S. Higgins, eds., 1984); Animal Cell Culture (R. Freshney, ed., 1986); Perbal, A Practical Guide to Molecular Cloning (1984). By using these conventional tools, one of skill in the art can readily identify the region of the polynucleotide that encodes for the catalytic active site of SEQ ID NO: 2 and modify a parental nucleic acid without undue experimentation while retaining its catalytic activity characteristic of a cysteine protease. For example, Applicants have provided in a prior Response a GenBank protein domain analysis showing that the claimed polypeptide has an active site comprised of a histidine and cysteine diad which is characteristic of a cysteine protease (*see*, Office Action Response dated June 3, 2009, Exhibit A). Consequently, one having ordinary skill in the art would be able to practice Claims 1-4 and 17-21 without undue experimentation because they would be able to modify the claimed polynucleotides and polypeptides while maintaining the integrity (e.g., activity) of the cysteine protease domain. Based on at least these noted reasons, Applicants believe that Claims 1-4 and 17-21 fully comply with the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 1-4 and 17-21 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 1-4 and 17-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Office Action

alleges that the instant specification fails to teach the claimed genus of polynucleotides encoding proteins with cysteine protease activity. Applicants respectfully traverse this rejection for at least the reasons set forth below.

An adequate written description of a claimed genus need provide "relevant, identifying characteristics" sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention (MPEP §2163). The Enzo court, citing the Guidelines, stated that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...complete or partial structure, other physical chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics.'" *Enzo Biochem, Inc. v. Gen-Probe, Inc.* (323 F.3d 956, 964 (Fed. Cir. 2002) (emphasis in original). Further, the Guidelines set forth that a relevant identifying characteristic can be stated in terms of a function. For example, the Guidelines state as follows:

> For example, if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of a function and minimal structure when there is a well-established correlation between structure and function. MPEP §2163.

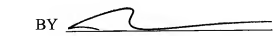
In the instant application, Applicants respectfully submit that the claimed polypeptides are sufficiently described based on identifying characteristics shared among the genus of claimed polypeptides, *i.e.* the feature of having a cysteine protease active site, which correlates the structure of the claimed polypeptides with their function as a cysteine protease. Meanwhile, the Examiner asserts that the specification fails to teach the active site of the protein of SEQ ID NO: 2. However, as shown by GenBank protein domain analysis, the polypeptide of SEQ ID NO: 2 comprises a conserved active site. This active site is comprised of a histidine and cysteine diad and is characteristic of a cysteine protease (*see*, Office Action Response dated June 3, 2009, Exhibit A). As such, Applicants have identified a feature (*i.e.* a histidine and cysteine diad) shared by all members of the claimed genus that correlates with their function as a cysteine protease. Therefore, the instant specification contains adequate written description for the claimed genus. Accordingly, Applicants respectfully submit that the rejection of Claims 1-4 and 17-21 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

K&L GATES LLP

BY 

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